English Instructions for use: Straumann® Emdogain®

CAUTION: U.S. federal law restricts this device to sale by or on the order of a dental professional.

1. Product description

Straumann® Emdogain® is a resorbable, implantable material and supports periodontal regeneration, which takes place over more than a year. It consists of hydrophobic enamel matrix proteins extracted from developing embryonal enamel of porcine origin in a propylene glycol alginate carrier. The gel has a suitable viscosity to facilitate application directly onto root surfaces exposed during periodontal surgery. Once applied onto an exposed root surface the protein self assembles into an insoluble three-dimensional matrix and creates a suitable environment for selective periodontal cell migration and attachment, which re-establishes lost tooth supporting tissues. Subsequent to formation of new attachment, alveolar bone can also be regenerated due to the osteogenic capacity of the restored periodontal ligament. Emdogain® is degraded by enzymatic processes of normal wound healing.

Straumann® Emdogain® is supplied in pre-filled, ready-to-use sterile syringes and available in three sizes (0.15 ml, 0.3 ml, 0.7 ml of the gel). The different filling sizes allow adapting the amount to the size and number of defects in one single patient as part of one surgical session. Each (pre-filled) syringe is meant for single use in one patient only.

The following procedure packs are offered for customer convenience:

- Straumann® Emdogain® Multipack: combination of 3 syringes with Emdogain® (either 0.3 ml or 0.7 ml filling volume) together with 3 syringes of Straumann® PrefGel®.

2. Intended use

Emdogain® is intended for topical application in conjunction with periodontal / peri-implant surgery to provide for regeneration of tooth / implant support lost to periodontal / peri-implant disease or trauma.

Straumann® Emdogain® may be used to support the soft tissue wound healing processes as part of oral surgical procedures.

3. Indications

- Emdogain® has been shown to be effective in sites with periodontal pockets more than 6mm associated with vertical bone loss on radiograph greater than 3 mm.
- Emdogain® has also been shown to be effective with furcation involvements exceeding 2mm but not through-and-through defects.
- Emdogain® used in recession defects has been shown to offer a potential for improved root coverage compared to the use of a coronally advanced flap alone, good aesthetic outcome, a gain in keratinized tissue and a potential for regeneration of attachment.
- Emdogain® is also indicated for use in extraction sites.
- Emdogain® is indicated to support healing of clean and non-inflamed wounds of the gingiva and oral mucosa resulting from surgical incisions (e.g. mucoperiosteal flaps).
- Straumann Emdogain® has been shown to enhance the positive outcome of surgical peri-implantitis therapy, improving the clinical outcome of the affected implant. Adding Emdogain® to the remedial treatment of peri-implant disease enhance the positive outcome of surgical peri-implantitis therapy.

4. Contraindications

Based on the results of the risk analysis the following patient population are contraindicated: patients with disorders or conditions including, but not limited to the following: uncontrolled diabetes or other uncontrolled systemic diseases, disorders or treatments that compromise wound healing, chronic high dose steroid therapy, bone metabolic diseases, radiation or other immuno-oppressive therapy and infections or vascular impairment at the surgical site.

5. Side effects, interactions and precautions; complications with Straumann products

In rare cases, clinical studies have reported the occurrence of general, procedure-related adverse events including but not limited to gingival bleeding, hematoma, infection, root (hyper)sensitivity, small wound dehiscence, mucosal irritation (soreness, pain, swelling) and aphta-like lesions.

6. Warnings

Immunological studies suggest that a small number of patients may become sensitized to Emdogain® as a result of repeated use. Please use caution in patients predisposed to allergic reactions and follow patients receiving repeated use closely. Post-market experience has indicated that the sensitization adverse reaction rate is low. Required treatment has ranged from no intervention needed to analgesics and/or antihistamines. The safety and effectiveness of Emdogain® has not been established in patients undergoing anticoagulant therapy. Careful consideration should be given before using Emdogain® for these patients. Gain of tooth support occurs only to the level of the root surface covered by the repositioned oral soft tissue. Therefore, Emdogain® should be used in areas where there is adequate tissue for root coverage. Emdogain® should be used only after plaque and calculus have been removed from the diseased site.

7. Caution/Precautions

- Do not use if sterile package is opened or damaged. To prevent possible cross contamination discard or return damaged package and the enclosed device.
- Syringe and application device are single use items. Do not re-sterilize or reuse syringe or application device. Each (pre-filled) syringe is intended for use in one patient only. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury or serious illness of the patient.
- The product should be stored at 2 – 8 °C upon arrival.
- Site-specific anatomy, surgical management, wound stabilization during healing, and post-surgical oral hygiene are critical factors for success.
- Be aware that bending the cannula when it is attached to the syringe may cause breakage of the syringe.
- Emdogain® should NOT be placed in untreated infected extraction sites. The practitioner should be confident that any active or recent infection and/or inflammation has been properly treated before start of the regenerative procedure. In extraction sockets proper treatment may include thorough debridement and removal of any infected granulation tissue from the extraction site.

8. Note

Separation of Straumann® Emdogain® may occur. Separation of Straumann® Emdogain® is identified as a non-homogeneous gel. Homogenization of the separated material can be achieved by shaking down the gel from the top to the bottom of the syringe, turn around the syringe and repeat the procedure ten to fifteen times until homogenization returns.

9. Procedure

1. Take out Emdogain® from cold storage approx. 30 minutes before use and allow it to assume ambient temperature.
2. Depending on the production lot, Emdogain® might either be supplied in a syringe with tamper-evident closure system or with a screw cap closure system. The tamper-evident closure system can be opened by holding the syringe upright on the ribbed part of the white closure

system. Gently tilt back and forth the cap to break the seals and remove by pulling upright. Avoid rotation.
In case of screw cap closure system: open the syringe by unscrewing the tip cap counter clock wise and gently remove the closure cap by pulling it.

3. Carefully attach the supplied application cannula.
4. Use the Emdogain® within 2 hours and discard any remaining gel.

In conjunction with conventional periodontal surgery:

1. Anaesthetize the area selected for surgery by block and/or infiltration anesthesia. Avoid injection with a vasoconstrictor into the interdental papilla or marginal gingiva.
2. Make intracrevicular incisions. Then, if judged appropriate, make one or two vertical releasing I cisions extending out into the alveolar mucosa. Raise full-thickness (mucoperiosteal) flaps on the buccal and palatal/lingual surfaces of the teeth. Preserve as much of the gingival connective tissue in the flap as possible. Maintain viability of periodontal cells by hydration of the soft tissue with saline.
3. Only remove the granulation tissue adherent to the alveolar bone and any associated osseous defects necessary to provide full access and visibility to the root surfaces. Remove subgingival plaque and calculus. Remove remaining smear layer by a quick surface cleaning with Straumann® PrefGel® (EDTA) for 2 min or 15 s with citric or phosphoric acid. Rinse thoroughly with sterile saline. Avoid contamination of the surgical area with saliva or blood after the final rinse.
4. Immediately apply Emdogain® onto the exposed root surfaces, starting at the most apical bone level. Apply Emdogain® to fully cover the exposed root surface areas. (Overflow of surplus material during suturing should occur).
5. Complete coverage of the interproximal area and optimal soft tissue adaptation is essential. If deemed appropriate, a periosteal fenestration at the base of the flap may be used to facilitate coronal repositioning of the soft tissue. Suture materials appropriate for extended stable closure should be preferred. Wound stability is critical to the outcome of a regeneration procedure using Emdogain®. If the linkage between the root surface and the healing connective tissues is broken, the periodontal defect will readily epithelialize resulting in a clinical failure.
6. The patients should be advised to rinse daily with an antiseptic mouth rinse (e.g. 0.1–0.2 % chlorhexidine solution) until 3 – 6 weeks post-surgery. Antibiotics may also be used if deemed appropriate based on the clinician's judgement.
7. The patient should be instructed not to brush in the area where surgery has been performed until 3weeks postoperatively. Then only gentle brushing on buccal and lingual surfaces using the "roll-stroke" method is recommended. No sulcular or interproximal tooth cleaning must be performed until 6 weeks postoperatively.
8. Sutures may be removed when the flaps and the root/soft tissue interface are stable, usually within 2 – 3 weeks. Consistent with conventional post-surgical care all patients should be reinstructed in proper oral hygiene measures as needed. Healing of clinical attachment and alveolar bone has been shown to continue for more than a year, and care should be taken not to interfere with this process.

In conjunction with coronally advanced flap for treatment of recession type defects:

1. Anesthetize the area selected for surgery by infiltration and, if needed, block anesthesia. Avoid injection of local anesthetic with vasoconstrictor into the interdental papillas or marginal gingiva.
2. Plan and scale the exposed root surface to remove plaque, calculus, root surface irregularities and, if judged appropriate, to reduce prominence.
3. Make a sulcular incision at the site of the recession. Extend the incision horizontally into the adjacent interdental area slightly coronal to the CEJ.
4. Make two vertical divergent releasing incisions at the mesial and distal line angles connected to the horizontal incision.
5. Raise a full-thickness (mucoperiosteal) flap until the mucogingival junction is passed.
6. Make a cut through the periosteum and continue to raise a split-thickness flap by means of a blunt dissection. The aim is to eliminate any muscle tension on the flap margins and allow for a passive and tension-free coronal positioning of the flap at the level of the CEJ.
7. De-epithelialize the buccal aspect of the interdental papillas to create a connective tissue bed for suturing the coronally advanced flap.
8. Condition the exposed root surface with Straumann® PrefGel® (EDTA) for 2 min. or 15 s with citric or phosphoric acid. Rinse thoroughly with sterile saline. Avoid contamination of the conditioned root surface with saliva or blood after the final rinse.
9. Immediately apply Emdogain® to fully cover the exposed and conditioned root surface.
10. Coronally position the flap and secure it at the level of the CEJ by suturing the flap into the recipient bed, i.e. the de-epithelialized papillas. Also close the vertical incisions with lateral sutures. Use suture materials for extended stable closure. No pressure should be applied to the flap after suturing.
11. The patient should be advised not to brush in the area, but rinse daily with an antiseptic mouth rinse (e.g. 0.1–0.2 % chlorhexidine solution) until 3weeks post-surgery. Patients should also be instructed to avoid muscle traction or other trauma to the treated area for the same period.
12. Sutures are removed when clinical healing of the flap is stable and sutures no longer add to wound stability.
13. After the initial healing period, patients are instructed in a tooth cleaning technique, which minimizes apically directed trauma on the gingival margin/soft tissues of the treated tooth. After 4–6weeks patients can gradually return to normal tooth cleaning measures.

In conjunction with oral surgical procedures to improve soft tissue wound healing:

- In conjunction with oral surgical procedures to improve soft tissue wound healing Emdogain® can be used to support soft tissue wound healing of surgical wounds as part of typical oral surgical procedures such as flap surgery, dental implantation procedures, soft tissue grafting procedures and gingivectomy procedures. In these procedures Emdogain® is applied on the complete wound area and wound margins of the surgical wound before flap closure and final suturing. Residual Emdogain® can be used to be applied on the wound margins after wound closure. Emdogain® gel oozing out of the wound margins can be removed if considered necessary.
- In case of gingivectomy procedures like tissue graft procedures or periodontal gingivectomy procedures that may not require suturing Emdogain® can be applied on the wound margins to facilitate wound healing as the final step of the procedure.
- Suture materials should be used for extended stable closure. No pressure should be applied to the flap after suturing. The patient should be advised not to brush in the area, but rinse daily with an antiseptic mouth rinse (e.g. 0.1–0.2 % chlorhexidine solution) until 3 weeks post-surgery. Patients should also be instructed to avoid muscle traction or other trauma to the treated area for the same period.
- Sutures are removed when clinical healing of the flap is stable and sutures no longer add to wound stability.

In conjunction with bone graft material:

In cases of wide defects, extraction sites or where soft tissue support is desired, Straumann® Emdogain® can be used in conjunction with a bone graft material.

- When combined with bone graft materials Straumann® Emdogain® is added drop-wise to the bone substitute and the resulting product is mixed with a spatula or other instruments suited for mixing until the mix gets a paste-like/wet coarse sand consistency that is suited for the application.
- The defect should be filled as completely as possible with the resulting mixture. Overaugmentation should be prevented. The bone graft should be gently compacted in the defect to ensure mechanical stability against compression. Too much pressure that would result in crushing the bone graft particles should be avoided.
- In the case of extraction sites placement of the Emdogain® bone graft mixture should be followed by closure of the extraction site to ensure the biomaterial is retained in the extraction socket. Closure may be carried out by placement of collagen substrates or soft tissue grafts followed by fixation through suture. In case of augmentation of vestibular dehiscences as part of simultaneous implantations Emdogain® bone graft mixtures may be covered by a membrane and covered by a coronally advanced flap. Complete closure of the flap to prevent membrane exposure are advised.
- To improve soft tissue wound healing a layer of Straumann® Emdogain® is applied on top of the bone graft augmentate immediately before final wound closure.
- In case of periodontal root surface treatments Straumann® Emdogain® should be applied on the root surface prior to the application of the bone graft or bone graft/Straumann® Emdogain® mixture to ensure proper coverage of the root surface with Straumann® Emdogain®.

In conjunction with collagen matrices:

Straumann® Emdogain® is compatible with collagen matrices, such as collagen membranes, collagen scaffolds, acellular dermal matrix grafts, or other soft tissue graft materials. The combination may be used in wide osseous defects to improve graft material containment, improve mechanical retention of mucogingival flaps as part of recession coverage procedures, or improve soft tissue thickness as part of mucogingival procedures.

- If considered appropriate, Straumann® Emdogain® can be used to precoat the collagen materials prior to application. Individual recommendations for presoaking given by the individual manufacturer should be considered before the collagen materials are combined with Straumann® Emdogain®.
- If considered appropriate, and depending on the individual procedure, the collagen material can be pinned or sutured in order to improve its mechanical stability and the stability of the underlying augmentate. After final placement of the collagen materials, and immediately before final flap closure, a layer of Straumann® Emdogain® can be applied evenly on top of the material.
- During periodontal root surface and root coverage treatments, Straumann® Emdogain® should be applied to the root surface prior to the application of the collagen material or collagen material precoated with Straumann® Emdogain® to ensure proper coverage of the root surface with Straumann® Emdogain®.

In conjunction with peri-implantitis surgical treatment:

1. The patients need to have had full-mouth debridement at least 1 month prior to surgery and to demonstrate adequate plaque control.
2. Anaesthetize the area selected for peri-implant treatment by block and/or infiltration anesthesia using anesthetic containing a vasoconstrictor such as adrenaline. Anesthesia should be placed apical to the pocket and pointing away from the pocket. Avoid injection with a vasoconstrictor into the interdental papilla or marginal gingiva.
3. Elevate full-thickness flaps to allow for adequate flap mobilization that supports defect visualization and coronal advancement at the time of closure.
4. Perform surface decontamination in conjunction with thorough debridement of the hard tissue defects and implant surface. Apply PrefGel® in the pockets for 2 minutes, then use saline solution to rinse it thoroughly
5. Apply Emdogain® carefully to the decontaminated implant surface, avoiding contamination with saliva or blood.
6. Fill the defects with a bone grafting material.
7. To provide a barrier function, apply either a resorbable collagen membrane, or a subepithelial connective tissue graft harvested from the palate.
8. Apply sutures.
9. Place patients on systemic antibiotics for postoperative infection control. Observe post-operative care according to the standards for surgical peri-implantitis treatment.

10. Healing phase

Please refer to the specific procedure part at section 9.

11. Further Information

Please refer to Straumann website for additional information.

Practitioners should contact Institut Straumann AG directly or any affiliate, local subsidiary or any 3rd party distributor through which the product may have been supplied in case of unwanted or unexpected effects that may be observed during or after use of the product.

12. Please note

Practitioners must have knowledge of Periodontology and instruction in the handling of the Straumann product described herein ("Straumann Product") for using the Straumann Product safely and properly in accordance with these instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Product is part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company ("Straumann"), except if stated otherwise for the respective Straumann Product. If use of products made by third parties is not recommended by Straumann, any such use will void any warranty or other obligation, express or implied, of Straumann.

13. Validity

Upon publication of these instructions for use, all previous versions are superseded.

14. Availability

Some items of the Straumann® regenerative portfolio are not available in all countries.

Symbols

The following table describes the symbols that may be printed on the packaging label.

Please refer to the packaging label for the applicable symbols related to the product.

Symbol	Symbol Description	Symbol Source
	Consult instructions for use *Follow the link to the eIFU: ifu.straumann.com*	ISO 15223-1
	Manufacturer	ISO 15223-1
	Date of manufacture	ISO 15223-1

Symbol	Symbol Description	Symbol Source
CE	CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC legislation. *Where applicable: The identification number of the Notified Body shall follow this symbol.*	MDR (EU) 2017/745
EC REP	Authorized representative in the European Community	ISO 15223-1
EC IMP	Indicates the entity importing the medical device into the European Union	Institut Straumann AG
REF	Catalogue number	ISO 15223-1
LOT	Batch code	ISO 15223-1
SN	Serial number	ISO 15223-1
MD	Medical device	Institut Straumann AG
2	Do not re-use	ISO 15223-1
11	Do not use more than 10 times	Institut Straumann AG
21	Do not use more than 20 times	Institut Straumann AG
NON STERILE	Non-sterile	ISO 15223-1
STERILE R	Sterilized using irradiation	ISO 15223-1
STERILE EO	Sterilized using ethylene oxide	ISO 15223-1
STERILE A	Sterilized using aseptic processing techniques	ISO 15223-1
	Single sterile barrier system	ISO 7000
	Single sterile barrier system with protective packaging inside	ISO 7000
	Double sterile barrier system	ISO 7000
2	Do not resterilize	ISO 15223-1
	Do not use if package is damaged	ISO 15223-1
	Keep away from sunlight	ISO 15223-1
Rx only	U.S. federal law restricts this device to sale by or on the order of a dental professional.	21 CFR 801.109(b) (1)
Qty.:	Quantity	Institut Straumann AG
Pat.:	Patent Marking *Follow the link to the patent information: pat.straumann.com*	Institut Straumann AG
	Use-by date	ISO 15223-1

Symbol	Symbol Description	Symbol Source
e.g.:	Temperature limit (e.g.: min 5 °C / max. 20 °C)	ISO 15223-1
e.g.:	Upper limit of temperature (e.g.: max. 20 °C)	ISO 15223-1
e.g.:	Lower limit of temperature (e.g.: min. 5 °C)	ISO 15223-1
	Keep dry	ISO 15223-1
	Caution	ISO 15223-1
	Contains hazardous substances	ISO 7000
BIO	Contains biological material of animal origin	ISO 7000
custom-made device	Custom-made device	MDR (EU) 2017/745